Individual Safety Report

3516711-6-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

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Approved by FDA on [illegible]

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	43 yrs or Date of birth [redacted]	(X) female ( ) male	137 lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
(X) required intervention to prevent permanent impairment/damage
(X) other: none

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
1/99	06/16/00

5. Describe event or problem

Consumer alleges that the use of Extra Strength TYLENOL® acetaminophen Gelcaps was associated w/LIVER DAMAGE (liver has had some damage). Consumer reports taking 4000 mg of TYLENOL daily since 1985 for fibromyalgia & rheumatoid arthritis. On approx 1/99, consumer reports having a liver profile taken, which was abnormal (LIVER FUNCTION TESTS ABNORMAL). At that time, MD reportedly advised consumer to have her liver profile checked every 3 months. Also, consumer reports that MD started her on ZOCOR® for a cholesterol level of 286. Since that time, consumer reports her moods have changed (EMOTIONAL LABILITY) & she is forgetful (AMNESIA). On approx 4/4/00, consumer reports consulting a neurologist for headaches. MD reportedly performed several unspecified tests, which included a liver profile. According to consumer "the white blood cell count in my liver was too high". MD reportedly advised pt to d/c use of PREMARIN® & start DEPAKOTE® & PHENERGAN® to treat her headaches. MD reportedly told consumer that TYLENOL was "killing her" & (See Sect B6)

6. Relevant tests/laboratory data, including dates

approx 1/99: unspecified liver tests were "abnormal"; approx 4/4/00: unspecified liver tests "abnormal", cholesterol=286 (Sect B5 cont) she needed to "wean" herself off the TYLENOL. Addl info rec'd 6/15/00: Phone call from (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

fibromyalgia, rheumatoid arthritis, diabetes, headaches; allergic to sulfa medications, penicillin, morphine, IVP dye DEMEROL®, TORADOL®; sensitive to "inflammatory medicines" (Sect B6 cont) consumer indicated that she has stopped taking TYLENOL & is experiencing HEADACHES & LEG CRAMPS. She also reports that "her red blood cells are not(See Sect C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Gelcaps
#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate)
#1 1000 mg, qid, po	#1 1985-5/00; approx 15yrs
#2	#2

4. Diagnosis for use (indication)

#1 fibromyalgia & rheumatoid arthritis
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

ZOCOR® (started 1/99), KLONOPIN®, PREMARIN® (stopped approx 4/1/00); (Sect B7 cont) normal" (BLOOD DYSCRASIA). In 5/00, MD reportedly performed EEG, MRI & unspecified blood tests. Consumer reports MD's diagnosis:"memory disorder MIGRAINE".

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(X) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr)	5.
06/15/00	(A) NDA # 19-872 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 1

8. Adverse event term(s)

LIVER DAMAGE — LIVER FUNC ABNO
EMOTIONAL LABIL — AMNESIA
HEADACHE — CRAMPS LEG
BLOOD DYSCRASIA — MIGRAINE

9. Mfr. report number

1350113A

E. Initial reporter

1. Name, address & phone #

DSS

JUN 21 2000

JUN 20 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or